PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing *(day/month/year)*	04.10.2000 4/11/01
Applicant's or agent's file reference: P097	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/GB99/04027	01/12/1999	01/12/1998

International Patent Classification (IPC) or both national classification and IPC

C07K14/705

Applicant

ABERDEEN UNIVERSITY et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain document cited
VII	☐	Certain defects in the international application
VIII	☒	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 01/04/2001.

Name and mailing address of the international preliminary examining authority:

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Authorized officer / Examiner

Stolz, B

Formalities officer (incl. extension of time limits)

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I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-26 as originally filed

Claims, No.:

1-23 as originally filed

Drawings, sheets:

1/6-6/6 as originally filed

2. The amendments have resulted in the cancellation of:

☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4, 7-9, 18
Inventive step (IS)	Claims	1-21
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

1. Reasoned statement

1.1. The application describes peptides derived from Rhesus D and Cc/Ee antigens. The peptides are useful in immunotherapy and may be used to produce immune responses.

1.2. Novelty (Art. 33(2) PCT)

Claim 18 lacks novelty in view of Barker et al., 1997 (Table 3)(D1).

The usefulness of epitopes derived from Rhesus D and Cc/Ee proteins in immunotherapy and in the induction of immune responses has been described in D1 and in Stott et al., 1998 (D2). This prior art implicitly considers the use of such peptides in pharmaceutical compositions. These two documents anticipate thus the subject matter of generic claims 1 to 4, 7 to 9.

1.3. Inventive step (Art. 33(3) PCT)

The remaining claims refer to the use of specific peptides derived from Rhesus D or Cc/Ee proteins for the indicated purposes. D2 mentions peptides 2, 12, 12a, 15a, and 28 to be stimulatory in over 40% of donors and suggests them to be suitable for the claimed purposes. Apart from the sequences of the listed peptides, the disclosure of D2 corresponds to the disclosure of the instant application. No inventive skills would be needed to combine the teaching of D2 with that of D1, in order to figure out the corresponding sequences of peptides 2, 12 or 28. The further features specifying the pharmaceutical compositions are considered to be within easy reach of the person of skill. The IPEA is therefore of the opinion that the subject matter of claims 5, 6, 10 to 17, 20 and 21 lacks inventive step.

In view of the disclosures of D1 and D2, making peptides 2, 12, and 28 obvious for the claimed purposes, any further Rhesus D or Cc/Ee derived peptides could only meet the requirements of inventive step if associated with an unexpected effect when compared with peptides 2, 12 or 28. At present, it is not clear if any of the additional peptides listed would meet this requirement.

2. Certain observations

2.1. Claims 1, 2 and 8 refer to analogues and derivatives of defined peptides. The terms "analogue" and "derivative" are open to interpretation and render the scope of the claims unclear. Furthermore, the description does not disclose any such derivative or analogue.

2.2. Several claims refer to peptides identified by numbers. These should be replaced by reference to Seq. ID numbers. Furthermore, it is noted that some numbers (such as 12) cannot be unambiguously assigned to only one sequence.

2.3. Claims 13 to 16 refer to pharmaceutical compositions comprising a peptide fragment. The claims should be worded accordingly. A peptide cannot be defined by reference to its location.

2.4. In view of D1 and D2, claims 1 to 4 and 7 to 9 merely define the goal to be achieved without telling the person of skill how to achieve it.

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Correspondence with the EPO on PCT Chapter II demands

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One of these labels should be affixed to a prominent place in the upper part of the letter or form etc. which you are filing.